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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,524	06/25/2003	Neil M. Cowen	50,528A	4984

25212 7590 05/04/2006

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INDIANAPOLIS, IN 46268

EXAMINER

KUMAR, VINOD

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,524

Applicant(s)

COWEN ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 4, 7, 11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction Election

1. Applicant's election of Group I, claims 1-3, 5-6, 8-10 and 12-13 in the paper filed on January 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-3, 5-6, 8-10 and 12-13 in conjunction with SEQ ID NO: 1 are examined on merits in the instant Office action. Non-elected subject matter should be cancelled. This restriction is made FINAL.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed on April 19, 2004 is attached to the instant Office action.

Specification

3. The disclosure is objected to because of the following informalities:

Applicant should update the status of the provisional or non-provisional applications, by providing the US Patent number if allowed, or indicate if it is abandoned. For example, page 6, line 3 of paragraph 0022 cites a US Application serial number. The status of this application needs to be updated.

The use of the trademark "Qlax 11" on page 15, last line has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate action is required.

Claim Objections

4. Claims 2 and 5 are objected to because of the following informalities:

In claim 2, insert --.—at the end of claim.

In claim 5, "foreign of interest" does not read properly. It is suggested to insert -- coding sequence-- after "foreign" and before "of interest".

In claim 5, replace "a" after "comprising" with --the--.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-6, 8-10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected under 35 U.S.C. 112 as being indefinite in its recitation "a promoter operable in plants, an untranslated leader sequence, a foreign of interest, and a 3' untranslated region (3'UTR)", which is confusing, since it is unclear whether promoter, leader sequence, gene of interest and 3' UTR are operably linked. It is suggested to amend the claim to describe that these elements are operably linked without bringing in any new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 8, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological material comprising recombinant expression cassette pMYC3212. Page 8, paragraph 0028 of specification describes some of the components of pMYC3212 but not all. Since the biological material comprising pMYC3212 is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material comprising pMYC3212. The specification does not disclose a repeatable process to

obtain the biological material and it is not apparent if the biological material is readily available to the public. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological material has been deposited under the Budapest Treaty and that the biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit,

the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination.” The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2 and 3 are rejected under 35 U.S.C. 102 (b) as being anticipated by Paek et al. (NCBI, GenBank, Sequence Accession No. L35913, Published 26 August, 1994).

Claims are broadly drawn to an isolated DNA molecule as defined in SEQ ID NO: 1, or wherein “N” at positions 65, 159 and 269 of said DNA molecule are all “G”

Paek et al. teach a DNA molecule comprising a nucleotide sequence which is identical to instant SEQ ID NO: 1, and comprises “G” residue at positions 985, 1079 and

1189 which correspond to positions 65, 159 and 269, respectively in the instant SEQ ID NO: 1.

Accordingly, Paek et al. anticipate claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 5-6, 8-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paek et al. (NCBI, GenBank, Sequence Accession No. L35913, Published 26 August, 1994) in view of Ingelbrecht et al. (The Plant Cell, 1:671-680, 1989).

Claims are broadly drawn to an isolated DNA molecule as defined in SEQ ID NO: 1, or wherein "N" at positions 65, 159 and 269 of said DNA molecule are all "G", or a recombinant expression cassette comprising a promoter, a gene of interest and 3' untranslated region (3'UTR) of said nucleic acid, or a transgenic plant comprising said expression cassette, or wherein transgenic plant is corn.

Paek et al. teach a DNA molecule comprising a nucleotide sequence which is identical to instant SEQ ID NO: 1, and comprises "G" residue at positions 985, 1079 and 1189 which correspond to positions 65, 159 and 269, respectively in the instant SEQ ID NO: 1.

Paek et al. do not teach a method for plant transformation comprising an expression cassette.

Ingelbrecht et al. teaches usefulness of using 3' untranslated region in enhancing the expression of a gene of interest in the transgenic plant. The reference teaches that 3' untranslated strongly influences the level of expression in a plant cell. The reference also teaches a method of transforming a plant cell and obtaining transgenic plant comprising an expression cassette. See page 671, abstract, introduction; page 672; page 673, figure 2; page 676, figure 4; page 678.

It would have been obvious to one of the ordinary skill in the art at the time claimed invention was made to operably link 3' untranslated region (3'UTR) of Paek et al. to any plant transformation expression cassette including the one taught by Ingelbrecht et al., which comprises a promoter operably linked with a gene of interest. Given that Ingelbrecht et al. teach the usefulness of using 3' untranslated region in expressing a gene of interest, one of the ordinary skill in the art would have been motivated to transform any known plant, such as corn plant with said expression cassette using any plant transformation method including the one taught by Ingelbrecht et al. to produce a transgenic plant with increased levels of any desirable gene product of interest with a reasonable expectation of success.

Conclusions

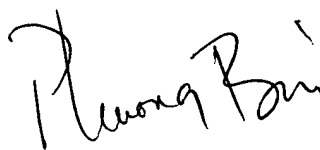
9. No claims are allowed.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


3/28/06
PHUONG T. BUI
PRIMARY EXAMINER